

Pfohl, Tim (TIC)

From: Phil Parrish <[REDACTED]>
Sent: Tuesday, November 29, 2011 9:42 AM
To: Noyes, Neal (TIC); Pfohl, Tim (TIC)
Subject: Re: got your message

Neal, thanks. From our point of view, the telecon scheduled with them later today is at the exploratory stage.

We are under the assumption that they wish to team with UVA and/or VCU on a proposal to the R&D Committee per the normal schedule, and go through the normal vetting process. There has been no decision yet regarding UVA teaming with them.

From: "Noyes, Neal (TIC)" <[REDACTED]>
Date: Tue, 29 Nov 2011 09:15:07 -0500
To: "Pfohl, Tim (TIC)" <[REDACTED]>, Phillip Parrish <[REDACTED]>
Subject: Re: got your message

Received business plan. No plan now to change funding cycle or avoid normal vetting process.

From: Pfohl, Tim (TIC)
Sent: Monday, November 28, 2011 07:21 PM
To: [REDACTED]; Noyes, Neal (TIC)
Subject: Re: got your message

I've not heard anything from Star. Maybe Neal has. Good news is we have some time before next round of R&D apps are due in March, though the company may want to move more quickly (as always!)

From: Phil Parrish [REDACTED]
Sent: Monday, November 28, 2011 04:16 PM
To: Pfohl, Tim (TIC)
Subject: Re: got your message

Hi Tim,

UVA is having a telecon with Star Scientific tomorrow, and I just wanted to check on whether you have now been contacted by them? They are apparently corresponding in some way with Jerry Kilgore about a potential joint project with UVA and/or VCU involving clinical trials. The topic is the potential for anatabine (a compound found in food crops and tobacco) to act as an anti-inflammatory.

I will be sitting in on the call, and can keep you apprised if you wish. We have been told (unconfirmed) that the governor's wife is gently advocating for them. I am certainly not the expert in this field; my interest will be focused on whether they are meeting the requirements for consideration for TIC support (location of production, when production would begin, matching, etc.)

Regards, Phil

Dr. Phillip A. Parrish
Associate Vice President for Research
University of Virginia
[REDACTED]
[REDACTED]



Potential research enterprise

John Clore to: jfstrauss, macrina, retchin

07/01/2011 03:43 PM

Dear all,, Just got off the phone with Paul Ladenson, Chair of Endocrine at Hopkins who wanted to explore our interest in participation in funded projects dealing with a tobacco alkaloid (anatabine) which is owned by John Williams (CEO of Star Scientific here in Richmond). Apparently the compound has potent antianflammatory effects (inhibits NFkB and virtually eliminates the inflammatory response of acute thyroiditis (which is why Ledenson got involved)) and Mr Williams specifically wants to fund projects in Virginia to test the compound. Mr Williams is very good friend with the Governor and the governor would like to sponsor these trials as evidence of Virginia's commitment to research and entrepreneurship. There would be a need for a GCRC-like venue as well as other CTSA resources which is why we were called. There is a meeting planned Saturday July 23 on Gibson Island in the Chesapeake Bay. Sounds like a unique opportunity. Your thoughts and insights are very much appreciated. John

John N Clore MD
Professor of Medicine
Associate Vice President for Clinical Research
Virginia Commonwealth University
1200 E Clay St
Suite 2000
Richmond VA 23298



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Re: Potential research enterprise

Sheldon Retchin to: John Clore

Cc: "[REDACTED]"

07/01/2011 06:39 PM

John:

It is hard to respond with any specificity because I don't know what's involved or whether they may be any particular conflicts that we should be sensitive of. Nonetheless, at this stage I can't think of a reason to not at least explore.

Sheldon

On Jul 1, 2011, at 3:43 PM, "John Clore" <[\[REDACTED\]](#)> wrote:

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[REDACTED]

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Re: Potential research enterprise

John Clore to: Sheldon Retchin

07/01/2011 07:06 PM

Cc: "Jerome F Jerome F Strauss Strauss", "Francis L Francis L Macrina Macrina"

Thanks. I wanted to be sure there weren't skeletons I was not aware of. Mr Williams is willing to fly me on his private jet and I wanted to be sure there were not reasons to keep distance. If I hear no further objections I will attend. John

From: Sheldon Retchin
Sent: 07/01/2011 06:36 PM EDT
To: John Clore
Cc: Jerome Strauss; Francis Macrina
Subject: Re: Potential research enterprise

John:

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Sheldon

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[REDACTED]

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Gibson island

John Clore to: Jerome F Jerome F Strauss Strauss, Sheldon M Sheldon M Retchin Retchin, Francis L Macrina

07/23/2011 08:44 PM

History: This message has been replied to.

Dear all. It was an interesting meeting. Jonnie williams has a nutraceutical (anatabine) which appears to have potent antiinflammatory effects. The Governor would like to use tobacco funds to support virginia research demonstrating the states committment to support research to reduce health care costs in the commonwealth. \$25 k planning grants are proposed towards submission of demonstration grants which have a very high likelihood of funding. jonnie would supplement this to the tune of \$2.5 - 4.0m. I am happy to discuss the possibilities. I proposed a study to pursue the effect of anatabine on progression to diabetes based on similar studies with salsalate which was enthuisiastically received. John

Re: Gibson island 
Francis L Macrina to: John Clore

07/24/2011 12:24 PM

John, Sounds very interesting. Are there any downsides, other than the collateral PR issues associated with being even remotely linked to the tobacco sector?

Frank

Francis L. Macrina, Ph.D.
Edward Myers Professor of Dentistry and
Vice President for Research
Virginia Commonwealth University

John Clore

Dear all. It was an interesting meeting. Jonnie wi...

07/23/2011 08:44:05 PM

From: John Clore/Notes/MCVH@MCVH
To: "Jerome F Jerome F Strauss Strauss" <[REDACTED]>, "Sheldon M Sheldon M Retchin Retchin" <[REDACTED]>, Francis L Macrina/HSC/VCU
Date: 07/23/2011 08:44 PM
Subject: Gibson island

Dear all. It was an interesting meeting. Jonnie williams has a nutraceutical (anatabine) which appears to have potent antiinflammatory effects. The Governor would like to use tobacco funds to support virginia research demonstrating the states committment to support research to reduce health care costs in the commonwealth. \$25 k planning grants are proposed towards submission of demonstration grants which have a very high likelihood of funding. jonnie would supplement this to the tune of \$2.5 - 4.0m. I am happy to discuss the possibilities. I proposed a study to pursue the effect of anatabine on progression to diabetes based on similar studies with salsalate which was enthusiastically received. John



Funding Opportunity

John Clore to: William N Roberts, Lenore Buckley, Robert DeLorenzo, Arun Sanyal, George Vetrovec, James Bennett3, John Nestler, Norbert Voelkel,
Cc: jfstrauss, macrina, retchin

07/25/2011 09:42 AM

Dear All I attended a meeting this weekend wherein an RFA was released towards applications to test a nutraceutical (Anatabine; Star Scientific) for inflammatory conditions(inhibits nFkB). Data presented by investigators from Johns Hopkins were compelling and I would be happy to discuss this further. But the company is requesting applications for \$25K planning grants. \$2.5m+ in funds from the Tobacco settlement are available for full grants stemming from the planning grants. If you might have an interest please let me know. John

John N Clore MD
Professor of Medicine
Associate Vice President for Clinical Research
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Richmond VA 23298



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**Anatabine redux****John Clore** to: Francis L Francis L Macrina Macrina08/29/2011 06:15 PM

Frank I have been invited to a reception at the governor's mansion tomorrow to announce the release of anatabloc and the awarding of 4 planning grants to conduct clinical trials with compound. Mine is one of them. Any reason not to go?

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Re: Anatabine redux
Francis L. Macrina to: John Clore

08/29/2011 09:04 PM

Congrats John
Certainly go
Frank

On Aug 29, 2011, at 6:15 PM, "John Clore" <[REDACTED]> wrote:

Frank I have been invited to a reception at the governor's mansion tomorrow to announce the release of anatabloc and the awarding of 4 planning grants to conduct clinical trials with compound. Mine is one of them. Any reason not to go?

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RE: Grant

Ryan Lanier to: John Clore

10/12/2011 10:20 AM

Default custom expiration date: 01/10/2012

History: This message has been replied to.

Hi John,

Thank you for the email. The deadline has not passed. We would like to receive your full application at your earliest convenience, as we will be entering a critical time period soon for putting the overall application together for the Virginia Tobacco Settlement Trust. However, I am still waiting for further details on how the proposals will be submitted to the VA Tobacco Settlement Trust, and I hope to have that information very soon.

At this point, I believe (and this could change...) we are going to gather each investigator's full proposal and submit them together in one application to be reviewed by the VA Tobacco Settlement Trust. It sounds as if this is the best way to get the funds from the state. Basically, this would be a general application for funds for research on anatabine as a potential anti-inflammatory agent. Those funds would be dispersed to the Universities involved (UVA and VCU), and you ultimately would receive funds for your project. Again, this involves several lawyers and government and university officials, so I'm waiting to hear exactly what they decide to be the best course of action.

Regarding anatabine, I have attached some information that I hope will be helpful. Unfortunately, we do not currently have pharmacokinetic data for anatabine dosing in humans at this time, but those studies are currently underway. In the meantime, please refer to information about our recommend dosing for clinical studies located on pp. 14-16 of the attached document named "Anatabine Investigator's Information."

Also, I would point you to the recent publication by Roskamp Institute scientists if you would like more info about pre-clinical work conducted with anatabine. The PubMed link is here:
<http://www.ncbi.nlm.nih.gov/pubmed/21958873>

We also have a patent application that was filed a few weeks ago that contains some additional information related to anatabine and effects on inflammation. If you would like to see this patent, let me know and I can send it to you in a separate email (it is a pretty big file).

There is some additional information (and data) pertaining to anatabine located on Rock Creek's Anatabloc website, in the link called "For Healthcare Professionals." A code is required to access the site, but I can acquire one for you if you would like access - just let me know. The website is here:
<http://anatabloc.com/for-healthcare-professionals/>

If you have any more questions about work that has been completed, don't hesitate to ask.

Best,
Ryan

From: John Clore [mailto:]
Sent: Wednesday, October 12, 2011 7:20 AM
To: Ryan Lanier
Subject: Grant

Dear Ryan, I hope the deadline for submission of a full application has not passed. I do intend to submit a proposal but need information on potential dosing levels and achievable drug levels. I would appreciate

any help you might be able to provide. Thanks John

John N Clore MD
Professor of Medicine
Associate Vice President for Clinical Research
Virginia Commonwealth University
1200 E Clay St
Suite 2000
Richmond VA 23298



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7.0 Anatabine Investigator's Information September 2011.pdf



Re: Fw: grant

John Clore to: rsterling

Default custom expiration date: 04/04/2012

01/05/2012 04:33 PM

Spoke to him a few nights ago and got the same answer.

John N Clore MD
Professor of Medicine
Associate Vice President for Clinical Research
Virginia Commonwealth University
1200 E Clay St
Suite 2000
Richmond VA 23298



-----Richard Sterling <rsterling@mcvh-vcu.edu> wrote: -----

To: [REDACTED] >
From: Richard Sterling <[REDACTED]>
Date: 01/05/2012 04:32PM
Subject: Fw: grant

Fyi

----- Original Message -----

From: Ryan Lanier [mailto:[REDACTED]]
Sent: Thursday, January 05, 2012 03:54 PM
To: Richard Sterling <[REDACTED]>
Subject: RE: grant

Hi Richard,

Sorry for the delay in getting back to you, but I am just getting back from holiday vacation. I hope your holidays were excellent, and that you are off to a great start in the new year.

You did send me a draft of your proposed studies, I believe in late September. We are still working out the details of the submission to the VA Tobacco Commission. Due to a number of unanticipated bureaucratic hurdles, our plans to submit the full application to the Commission before the end of 2011 was not realized. We are, however, continuing to work with officials at UVA and VCU and with the Tobacco Commission on the best course of action to secure funding for the proposed studies with anatabine. This involves lots of lawyers, as well as officials from both universities and the VA state government.

I hope to have more tangible news in the near future, but I suspect this may drag on for several more weeks before I have a firm answer for you. I'm sorry for the delay in getting any news to you, but what seemed like a very straightforward plan to secure funding (that appears ready for the taking) for this series of studies has gotten somewhat mired in a bureaucratic stranglehold.

Thanks again, and I will update you as soon as I can.

Best,
Ryan

-----Original Message-----

From: Richard Sterling [mailto:]

Sent: Monday, December 26, 2011 11:56 AM

To: Ryan Lanier

Subject: Re: grant

As 2011 comes to a close, I have still not heard anything about the grant submission process. I think I sent you a draft of what I plan to submit several weeks ago. Any idea of the time times for this?

Happy Holidays

R

On 9/26/2011 10:30 AM, Ryan Lanier wrote:

> Hi Richard,

>

> I am also still waiting on details about the application process for the

> VA Tobacco Settlement Trust funds. This is a matter that our counsel is

> working out with the universities that are involved, including UVA and

> VCU, as well as with government officials in VA. I would expect some

> news about this soon, but I honestly do not have a firm idea when that

> might be.

>

> At this point it appears that our company's (Rock Creek's) plan is for us not to be directly involved in supervising the projects. Rather, the

> studies will be supervised by the respective investigators and their universities.

>

> According to our general counsel, if you would like to use a third party

> either you or VCU will need to make sure that there is a confidentiality

> agreement in place that is as stringent as the one that you (and the

> university) signed before releasing any confidential information to that

> third party. This would be something that we would expect VCU to move

> forward on rather than us (Rock Creek). We would not have a problem with

> your working with a third party, as long as that confidentiality

> agreement is in place.

>

> Regarding HDL, I believe you are correct - you should not need another

> CDA with them.

>

> Does that make sense, or have I made it more confusing? Feel free to

> write me back or give me a call if you have any questions. I will be

> sure to pass on any information about the grant application process once

> I have it.

>

> Best,

> Ryan

>

> -----Original Message-----

> From: Richard Sterling [mailto:]

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From: "Ryan Lanier" [REDACTED] >
To: "Alanda R Perry/FS/VCU" [REDACTED] >
Date: 02/16/2012 09:32 AM
Subject: RE: Anatabine Study for Dr. Clore/VCU

Hi Alanda,

This is a little tricky, but in this case, Rock Creek will not be acting as the Sponsor. We are merely acting as facilitators for a grant application process. Dr. Clore's research proposal is one of several being collected from researchers at UVA and VCU to be submitted as one grant proposal to the Virginia Tobacco Commission (VTC) for funding. The purpose of the overall grant to the VTC is to provide funding for the conduct of studies in Virginia, by Virginia academic institutions, to evaluate whether the dietary supplement anatabine has effects on a number of health conditions characterized by chronic inflammation. Below is a brief description of how the process is envisioned to work.

Since grant applications to the VTC must be made by a not for profit entity, and since the majority of the applications were from UVA, we hoped that UVA would be willing to serve as the host facility for the grant. UVA would submit a grant to the VTC, administrate the grant, manage all funds and act as the host institution. Funded studies at other institutions (such as VCU) would be managed as collaborating investigators under the grant as per multi-site trials.

Rock Creek Pharma will provide scientific and toxicological information under CDA, and supplies at our cost. Rock Creek will ask for no funding, and expects to neither receive nor administer funding for this project. Again, we will not be acting as Sponsors for any study that receives funding via grant award from the VTC.

Does this make sense at all? I am sure it is very confusing! I have had some trouble keeping up with the twists and turns as we have worked on this project. And, it should be noted that the date that the application will be submitted is still TBD. We are still working on details of the process with officials in VA state government, and officials at UVA.

Sorry for the very long answer, but I wanted to spell it all out. Let me know if you have questions.

Kindest regards,

Ryan

From: Alanda R Perry/FS/VCU [<mailto:>]
Sent: Wednesday, February 15, 2012 2:47 PM
To: Ryan Lanier
Subject: Anatabine Study for Dr. Clore/VCU

Hi Ryan,

I'm reviewing a proposal from Dr. Clore entitled "The Effect of the Anti-Inflammatory Anatabine on Mechanisms of Type 2 Diabetes." I was wondering how Rock Creek typically handles WIRB fees. In general, VCU prefers to have the WIRB fees billed directly to the Sponsor, which cuts out the middle man and also saves the Sponsor the cost of paying indirects on top of the WIRB fees. Is this acceptable to Rock Creek? Feel free to give me a call if you would like to discuss this in more detail.

Alanda Perry, MA

Contract and Grant Administrator
Office of Sponsored Programs-Industry Support
Virginia Commonwealth University
800 East Leigh Street, Suite 113
Richmond, Virginia 23219
804-827-4996 (tel.)
804-827-0087 (fax)

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RE: grant
Ryan Lanier to: Richard Sterling

09/26/2011 10:31 AM

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Best,
Ryan

-----Original Message-----

From: Richard Sterling [mailto:]
Sent: Monday, September 26, 2011 9:01 AM
To: Ryan Lanier
Subject: grant

I have not gotten "official" word about details of the full proposal. When might I expect something. If timing is important, I was thinking of a 12 week study, rather than 24 weeks. I also need to know about budget limitations. Also, I want to work with someone at another University to do the fibrosis markers. Does he have to sign a CDA? If so, I need to get that paper work started. I will be using HDL here in Richmond for the cytokine analysis, but they already have a CDA and are working with you on another project, so i do not need to do anything else to include them in my proposal, correct?

--

Richard K. Sterling, MD, MSc
VCU Hepatology Professor of Medicine
Chief, Section of Hepatology

Division of Gastroenterology, Hepatology, and Nutrition
Virginia Commonwealth University Health System



Leave for Gibson Island

Sat 07/23/2011 7:00 AM - 8:00 AM

Location: MartinAir Charter Flights RIC

Description

Dr. Clore, Dr. Shupnik and Ms. Sutherland,

I have some further information regarding the plane that will be picking you each up and taking you to BWI for the symposium on Saturday. The plane will be stopping first at Richmond International Airport, at the Martinair, Inc. FBO. This is a change of FBO for you, Dr. Clore. The address for Martinair is:

Martinair, Inc.
5733 Huntsman Road
Richmond International Airport
804.222.7401

The plane's tail number is 804TF. You will be meeting Mary Shea Sutherland, who will also be attending the symposium. Departure from Martinair will now be **7:30am**, instead of 7:00am.

The plane will proceed to Landmark FBO at Charlottesville Albemarle Airport to pick up Dr. Shupnik, and will then fly to BWI airport to meet Mr. Williams, Dr. Mullan and Dr. Crawford for the drive to Gibson Island.

Please do not hesitate to contact me if you have any questions or need further assistance.

Kind regards,

Elizabeth

C. Elizabeth Pfeifer
Executive Assistant to
Paul L. Perito,
Chairman, President and COO
Star Scientific, Inc.
1250 24th Street, NW, Suite 700
Washington, DC 20037

 (office)

(fax)

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